MAR 1 6 2005

K04 3401
page 1 of 4

510(k) Summary

1) Submitter Information

Company Name:	The Spectranetics Corporation
Company Address:	96 Talamine Court Colorado Springs, CO 80907
Company Phone:	(719) 633-08333/(800) 633-0960
Company Fax:	(719) 442-2481
Contact Person:	Adrian Elfe V.P. QA/RA
Date Prepared:	11 February 2005

2) Identification

Device Trade Name:	Spectranetics Lead Locking Device E (LLD E).
Device Common Name:	Locking stylet
Classification Name:	Stylet, Catheter, CFR 870.1380
Device Class:	Class II
Device Code:	DRB

3) Identification of Predicate Devices

The Spectranetics LLD E stylets are similar in design, construction, indications, target population, risk analysis, performance, and materials to the predicate devices, the Spectranetics LLD stylets, K990713.

4) Device Description

The Spectranetics LLD E is a percutaneous wire stylets that are placed inside the central lumen of a pacemaker or defibrillator lead as a fixation mechanism to provide traction for the extraction of the lead.

The Spectranetics LLD E is comprised of two (2) wire loop handles and a core mandrel that has a stainless steel mesh fixation mechanism. This mesh is attached at the distal end within a radiopaque marker for visibility under fluoroscopy. The proximal end of the mesh is attached to a proximal connector that is used to deploy and lock the device into the pacing or defibrillator lead.

The proximal connector is seated on a crimped section of the core mandrel until it is deployed. The connector slides from the crimped section and deploys the mesh inside the lead.

The tip of the LLD E is comprised of a platinum/iridium coil that is affixed to the tapered tip with the use of tin/silver solder. This coil allows the stylet better maneuverability around tight curves as compared to the predicate device. The platinum/iridium materials of the coil also allow for visualization of the stylet tip under fluoroscopy.

5) Intended Use

The Spectranetics LLD E is intended for use in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads having an inner lumen and using the superior venous approach. The lead inner lumen must have an inner diameter (ID) range from 0.015 – 0.026 inches (0.38 – 0.66 mm) and a length less than 33.5 inches (85 cm).

6) Comparison to Predicate Device

Substantial Equivalence Summary:

The Spectranetics LLD E stylet is equivalent to the predicate device, the current Spectranetics LLD stylets, in materials design, and configuration, except for the following minor enhancements to the LLD E:

Wire Loop Handles:

The Spectranetics LLD E is comprised of two (2) stainless steel wire loop handles. The predicate devices (LLD stylets) are comprised of one stainless steel wire hoop handle and a stainless steel suture cleat. The second wire hoop on the LLD E fulfills the same function (serves as a suture tie down point) as the suture cleat on the predicate devices.

Dimensions:

The maximum tip diameter for the LLD E is 0.015 inches whereas the maximum tip diameters for the LLD # 1 and LLD #2 (predicate devices) is 0.013 and 0.017 inches respectively. The maximum body diameter for the LLD E is 0.015 inches whereas the maximum body diameter for the LLD #1 and the LLD #2 is 0.0135 and 0.0175 inches respectively.

Length:

The has a minimum working length of 85 centimeters whereas the predicate LLD devices have a minimum working length of 65 centimeters. Working length refers to the length of the locking mesh. The overall length of the LLD E stylet is equivalent to the overall length of the LLD stylets, 135 cm.

Distal Tip:

The tip of the LLD E stylet has been designed for more flexibility so as to improve the tractability of the stylet in pacing and defibrillator leads.

Tin/silver solder is used to secure a platinum/iridium coil to the distal tip of the LLD E stylet. The platinum iridium coil is approximately 1 centimeter in length and is wound over the stainless steel core mandrel. The coil is secured on its other end to the distal marker band by another tin/silver solder joint. Tin/silver solder is used to secure the stainless steel mesh braid to the distal marker band. The distal marker band is approximately 1 centimeter from the proximal tip of the LLD E stylet.

In contrast an epoxy plug is used to secure the stainless steel mesh braid to the tip of the stylet for the LLD predicate devices. Directly behind the epoxy plug is the distal marker band that is also secured to the stainless steel mesh braid and core mandrel by the epoxy adhesive. This design makes for a stiffer tip (approximately 2 cm.) that can limit the tractability of the predicate devices.

Bench Testing:

Physical testing was performed on the mechanical joints and overall design of the LLD E stylet to verify the physical properties of the device. Testing consisted of the following: fatigue testing the locking and unlocking performance of the stylet, tensile strength of the solder joints. Test results indicate that the samples tested passed the fatigue and strength test for the LLD E design.

Performance testing was conducted to verify the performance properties of the LLD E stylet. Testing consisted of lead tracking capability, and lead locking and unlocking capability using an anatomical model. Test results indicate that the LLD E stylet tracked through an anatomical model very well through both a simulated 0.015 inch ID and a 0.026 inch ID lead inner lumen. Test results also indicated that the LLD E adequately locked and unlocked both sizes of leads.

Shelf Life testing was conducted to verify the performance of the LLD E design after accelerated aging and shipping distribution testing was conducted to verify the acceptable function and appearance of the device and its packaging after simulated shipping. Acceptable function and appearance of the LLD E stylet design was confirmed after accelerated aging and shipping distribution testing.

Testing was conducted to confirm that the biocompatibility of the LLD E stylet is substantially equivalent to the predicate device, the LLD stylet. Test results indicate that LLD E is substantially equivalent to the LLD stylet design in regards to device biocompatibility.

Radiopacity testing was conducted to verify the radiopacity of the LLD E stylets. Test results indicate that the LLD E is more visible that the LLD stylets.

Conclusion:

The Spectranetics LLD E stylet is similar in basic design, construction, mechanical safety, indications, target population, risk analysis, performance, and materials to the predicate device. The Spectranetics New Product Introduction procedure has been faithfully followed in concert with the Quality System Regulations for new product introduction. The Company's design validation protocols, the Company's Risk Management System, and the Design Failure Mode Effects Analysis addressed all known risks associated with the device including tensile strength, bond joints, tracking, locking and unlocking, visibility, and biocompatibility. Testing performed for the LLD E provides reasonable assurance that the device will perform in a safe and effective manner when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

The Spectranetics Corp.
c/o Mr. Michael J. Ryan
RA Manager
96 Talamine Court
Colorado Springs, CO 80907-5186

Re: K043401
Trade Name: Spectranetics LLD E stylet
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter Stylet
Regulatory Class: Class II
Product Code: DRB
Dated: February 15, 2005
Received: February 16, 2005

Dear Mr. Ryan:

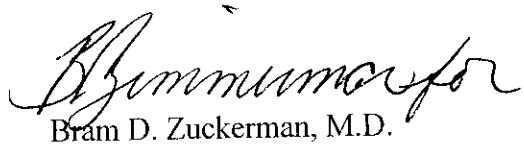
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043401

Device Name: Spectranetics LLD E Stylet

Indications For Use:

The Spectranetics LLD E is intended for use in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads having an inner lumen and using the superior venous approach. The lead inner lumen must have an inner diameter (ID) range from 0.015 – 0.026 inches (0.38 – 0.66 mm) and a length less than 33.5 inches (85 cm).

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043401